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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,579	08/25/1999	MICHAEL MEYRICK BURRELL	9341-018-999	6768

7590

11/19/2004

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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/383,579

Applicant(s)

BURRELL ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-37 is/are pending in the application.
- 4a) Of the above claim(s) 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 8/26/2004 has been entered.
2. Claims 19-37 are pending.

Claims 24-33 have been withdrawn from consideration for being drawn to non-elected inventions.

Claim 37 has been newly added.

3. Claims 19-23 and 34-37 including SEQ ID NO:9, are examined in the present office action.
4. Rejections and objections not set forth below are withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Information Disclosure Statement

6. References considered in the IDS filed 12/4/2003 that are also contained in the IDS filed 8/26/2004 were not initialed because they are duplicates.

The Stewart et al (1995) was not considered because the full citation was not provided and the information could not be ascertained from the supplied document.

Written Description

7. Claims 19-23 and 34-36 remain rejected and claim 37 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such

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a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/24/2004. Applicant's arguments filed 8/26/2004 have been fully considered but they are not persuasive.

Applicants contend that a person skilled in the art would readily appreciate that sequences that are homologous to Applicants' SEQ ID NO:9, including parts of the sequence, may also possess expansin activity (i.e., have an ability to modify tree height and/or internode length in transformed trees) and, as such, are included with the scope of the present invention (page 7, bottom paragraph).

The Office contends that Applicants have not disclosed an assay other than transforming a gymnosperm or dicot tree with said sequence to determine if said sequence causes the tree height and/or internode length to be decreased when said sequence is expressed in the tree. Applicants have not disclosed sequences, parts thereof, or homologues that "have an ability" to decrease tree height and/or internode length. "Have an ability" encompasses functions that Applicant has not disclosed. The claims are drawn to all sequences that are a part of SEQ ID NO:9 or are homologues of said sequence, but Applicants have only disclosed sequences that have expansin activity, i.e., over-expression of said sequences in a gymnosperm or dicot tree cause a decrease in tree height and/or internode length. Applicants have not disclosed "parts thereof" that have the specified activity. Applicants are not in possession of "parts thereof".

Applicants contend that the prior art teaches expansin sequences, and that the present specification presents nucleic acid sequences encoding seven expansin polypeptides (SEQ ID NO:1-6 and 9). Applicants contend that these sequences amply describe sequences that fall

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within the scope of parts of SEQ ID NO:9 and homologous sequences thereto (page 7, bottom paragraph).

The Office contends that the prior art teaches nucleic acid sequences encoding expansin proteins from cucumber, Arabidopsis, rice and pea (For example, see Shcherban et al (1995, PNAS 92:9245-9249, list in IDS). The Office contends that Applicants have only presented six nucleic acid sequences from Eucalyptus, that presumably encode expansin proteins and SEQ ID NO:9 from cucumber that encodes an expansin polypeptide of SEQ ID NO:10. Applicants have not disclosed parts of an expansin nucleic acid sequence, or homologous sequences that when expressed in a gymnosperm or dicot tree, decrease tree height and/or internode length.

Applicants contend that the Shcherban et al reference discloses several expansin proteins and sequence alignment that facilitate identification of conserved regions of an expansin sequence (parts) and homologous sequences thereto (page 8, 1st full paragraph).

The Office contends that Shcherban et al disclose conserved regions of expansin proteins. Applicants' claims do not include a functional limitation that is specific to Applicants' invention. The functional limitation "having an ability to modify tree height and/or internode length" is not commensurate with Applicants' disclosure. Applicants disclose transforming a dicot tree with nucleic acid sequences encoding an expansin protein wherein the expression of said sequence in a gymnosperm or dicot tree causes the gymnosperm or dicot tree to display a decreased tree height and/or internode length. Said functional recitation more accurately describes Applicants' invention. Having an "ability" reads on sequences that Applicants are not in possession. Applicants and Shcherban et al have not disclosed a "part of" a sequence that when transformed

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into a gymnosperm or dicot tree display a decreased tree height and/or internode length.

Applicants are not in possession of a "part of" a sequence.

Scope of Enablement

8. Claims 19-23 and 34-36 remain rejected and claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims drawn to a method of decreasing gymnosperm or dicot tree height and/or internode length comprising transforming a tree with SEQ ID NO:9 operably linked in sense orientation to the 35S promoter (page 21-22), does not reasonably provide enablement for claims broadly drawn to a method of transforming trees to modify fiber characteristics comprising transforming a plant with a nucleic acid sequence comprising SEQ ID NO:9, parts thereof, sequences substantially similar thereto and having the same function, or combinations thereof, or a seed of a tree transformed therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/24/2004. Applicant's arguments filed 8/26/2004 have been fully considered but they are not persuasive.

Applicants contend that the claim has been amended to clarify the functionality which is shared among polypeptides encoded by SEQ ID NO:9, parts thereof and sequences which have sufficient homology to hybridize thereto under the conditions specified in the claims. The functionality relates to the capability of modifying tree height and/or internode length (page 10, 1st paragraph).

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The Office contends the functional limitation “having an ability to modify tree height and/or internode length” is not commensurate with Applicants’ disclosure. This functional description encompasses sequences outside the scope of Applicants’ disclosure. Amending the claim to recite, “wherein said nucleic acid sequence encodes an expansin and wherein said nucleic acid decreases tree height and/or internode length in gymnosperm or dicot trees transformed therewith”, more accurately describes Applicants disclosed invention.

Applicants contend that the skill in the art of biotechnology is high and obtaining parts of SEQ ID NO:9 and/or homologues thereto and assaying polypeptides encoded therefrom for function does not constitute undue experimentation. Applicants contend that the information for manipulating such sequences and identifying such sequences is known in the art. Once attained, one skilled in the art can test the sequence to determine if it exhibits the claimed functional characteristics (paragraph bridging pages 10 and 11).

The Office contends that given the state of the art, and given the prior art and Applicants’ specification that teaches nucleic acid sequences encoding expansins, one skilled in the art can identify sequences which hybridize to Applicants’ SEQ ID NO:9 and test for functionality of the putative sequences by transforming a gymnosperm or dicot tree to determine if said transformed gymnosperm or dicot tree exhibits a decreased height and/or internode length when compared to a wild type plant of the same species. Given that the recitation “parts thereof” read on one base pair, undue trial and error experimentation would be required by one skilled in the art to identify and test the multitude of sequences encompassed by this recitation. Applicant is not enabled for “parts thereof”, as recited in claim 19, line 7.

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Applicants contend that the prior art and the present specification serve to reduce uncertainty involved in determining which residues and/or regions of an expansin sequence may be important for protein function (paragraph bridging pages 11-12).

The Office contends that the prior art and the present specification provide guidance for one skilled in the art to determine which residues and/or regions of an expansin sequence may be important for protein function. This information, along with information concerning transforming a gymnosperm or dicot tree with said sequence, to determine if said sequence transformed into a gymnosperm or dicot tree causes said gymnosperm or dicot tree to exhibit a decreased height and/or internode length, allows one skilled in the art to test for the appropriate function.

Applicants present a brief, parsed interpretation of the *Wands* factors. Applicants contend that some experimentation is sanctioned as long as it is not undue experimentation. Applicants contend that no working examples are required. Applicants contend that the Federal Circuit has specifically sanctioned a great deal of experimentation before the threshold into “undue experimentation” is crossed.

The Office contends that for “parts thereof”, undue experimentation would be required to practice the claimed invention, and is therefore, not enabled. Given the thousands of parts that make up the whole conserved region of expansins, as disclosed by Shcherban et al, one skilled in the art would have to isolate all the different parts, subclone the parts into expression vectors, and transform gymnosperm or dicot tree to determine which part of SEQ ID NO:9 can be used to practice the claimed invention.

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9. Claims 19-23 and 34-37 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method of transforming trees to decrease tree height and/or internode length comprising transforming a tree with SEQ ID NO:9 encoding SEQ ID NO:10.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
November 9, 2004

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600